

**Mississippi Secretary of State**  
700 North Street P. O. Box 136, Jackson, MS 39205-0136

**ADMINISTRATIVE PROCEDURES NOTICE FILING**

AGENCY NAME Division of Medicaid		CONTACT PERSON Margaret Wilson	TELEPHONE NUMBER (601) 359-5241	
ADDRESS 550 High Street, Suite 1000		CITY Jackson	STATE MS	ZIP 39201
EMAIL Margaret.Wilson@medicaid.ms.gov	SUBMIT DATE <b>MAR 31 2014</b>	Name or number of rule(s): Title 23: Medicaid, Part 203: Physician Services, Chapter 2: Physician-Administered Drugs and Implantable Drug System Devices, Rule 2.1: Covered Services, Rule 2.2: Drug Rebates and Rule 2.3: Botulinum Toxins A and B.		

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal: The MS Division of Medicaid's Administrative Code final filing is being submitted to (1) rename Miss. Admin. Code Part 203, Chapter 2 to Physician Administered Drugs and Implantable Drug System Devices and define these terms; (2) describe coverage which now includes drug wastage; (3) refer to the Miss. Admin. Code Part 200, Rule 4.10 340B providers effective 07/01/2014; and (4) add the diagnoses neurogenic detrusor over activity and chronic migraine headaches and remove nystagmus for the indication of indication for Botulinum Toxins A.

Specific legal authority authorizing the promulgation of rule: SSA § 1927(a)(7) and § 1927 (k)(2); 42 USC § 1396r-8; Deficit Reduction Act of 2005; 42 CFR Part 447; Miss. Code Ann. §§ 43-13-117, 43-13-121.

List all rules repealed, amended, or suspended by the proposed rule: Title 23: Medicaid, Part 203: Physician Services, Chapter 2: Physician-Administered Drugs and Implantable Drug System Devices, Rule 2.1, 2.2 and 2.3.

**ORAL PROCEEDING:**

☐ An oral proceeding is scheduled for this rule on Date: \_\_\_\_\_ Time: \_\_\_\_\_ Place: \_\_\_\_\_

☒ Presently, an oral proceeding is not scheduled on this rule.

If an oral proceeding is not scheduled, an oral proceeding must be held if a written request for an oral proceeding is submitted by a political subdivision, an agency or ten (10) or more persons. The written request should be submitted to the agency contact person at the above address within twenty (20) days after the filing of this notice of proposed rule adoption and should include the name, address, email address, and telephone number of the person(s) making the request; and, if you are an agent or attorney, the name, address, email address, and telephone number of the party or parties you represent. At any time within the twenty-five (25) day public comment period, written submissions including arguments, data, and views on the proposed rule/amendment/repeal may be submitted to the filing agency.

**ECONOMIC IMPACT STATEMENT:**

☐ Economic impact statement not required for this rule. ☒ Concise summary of economic impact statement attached

TEMPORARY RULES	PROPOSED ACTION ON RULES	FINAL ACTION ON RULES
_____ Original filing _____ Renewal of effectiveness To be in effect in _____ days Effective date: _____ Immediately upon filing _____ Other (specify): _____	<b>Action proposed:</b> _____ New rule(s) <input checked="" type="checkbox"/> Amendment to existing rule(s) _____ Repeal of existing rule(s) _____ Adoption by reference <b>Proposed final effective date:</b> _____ 30 days after filing <input checked="" type="checkbox"/> Other (specify): June 1, 2014	<b>Date Proposed Rule Filed:</b> _____ <b>Action taken:</b> _____ Adopted with no changes in text _____ Adopted with changes _____ Adopted by reference _____ Withdrawn _____ Repeal adopted as proposed <b>Effective date:</b> _____ 30 days after filing _____ Other (specify): _____

Printed name and Title of person authorized to file rules: David J. Dziela, Ph.D., Executive Director

Signature of person authorized to file rules: \_\_\_\_\_

<b>OFFICIAL FILING STAMP</b>  Accepted for filing by _____	<b>DO NOT WRITE BELOW THIS LINE</b> <b>OFFICIAL FILING STAMP</b>  Accepted for filing by <u>#20431</u> 	<b>OFFICIAL FILING STAMP</b>  Accepted for filing by _____
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The entire text of the Proposed Rule including the text of any rule being amended or changed is attached.



DELBERT HOSEMANN  
Secretary of State

### CONCISE SUMMARY OF ECONOMIC IMPACT STATEMENT

An Economic Impact Statement is required for this proposed rule by Section 25-43-3.105 of the Administrative Procedures Act. This is a Concise Summary of the Economic Impact Statement which must be filed with the Secretary of State's Office.

AGENCY NAME Division of Medicaid	CONTACT PERSON Margaret Wilson	TELEPHONE NUMBER 601-359-5248
ADDRESS Walter Sillers Building, Suite 1000	CITY Jackson	STATE MS
EMAIL Margaret.wilson@medicaid.ms.gov	DESCRIPTIVE TITLE OF PROPOSED RULE 2.1: Covered Services 2.2: Drug Rebates 2.3: Botulinum Toxins A and B.	
Specific Legal Authority Authorizing the promulgation of Rule: SSA § 1927(a)(7) and § 1927 (k)(2); 42 USC § 1396r-8; Deficit Reduction Act of 2005; 42 CFR Part 447; Miss. Code Ann. §§ 43-13-117, 43-13-121.	Reference to Rules repealed, amended or suspended by the Proposed Rule: Title 23: Medicaid, Part 203: Physician Services, Chapter 2: Injectable Drugs, Rule 2.1: Covered Services, Rule 2.2: Drug Rebates and Rule 2.3: Botulinum Toxins A and B.	

#### A. Estimated Costs and Benefits

- Briefly summarize the benefits that may result from this regulation and who will benefit:  
*Beneficiaries will continue to receive medically necessary Physician Administered Drugs and Implantable Drug System Devices. This filing adds language and clarification for Physician Administered Drugs and Implantable Drug System Devices.*
- Briefly describe the need for the proposed rule:  
*To create specific policy for Physician-Administered Drugs and Implantable Drug System Devices.*
- Briefly describe the effect the proposed action will have on the public health, safety, and welfare:  
*The proposed policy for Physician-Administered Drugs and Implantable Drug System Devices will provide increased access to care for needed services which will have a positive effect on the health, safety, and welfare of the public.*
- Estimated Cost of implementing proposed action:
  - To the agency  
☐ Nothing ☒ Minimal ☐ Moderate ☐ Substantial ☐ Excessive
  - To other state or local government entities  
☒ Nothing ☐ Minimal ☐ Moderate ☐ Substantial ☐ Excessive
- Estimated Cost and/or economic benefit to all persons directly affected by the proposed rule:
  - Cost:  
☐ Nothing ☒ Minimal ☐ Moderate ☐ Substantial ☐ Excessive
  - Economic Benefit:  
☐ Nothing ☐ Minimal ☐ Moderate ☒ Substantial ☐ Excessive
- Estimated impact on small businesses:  
☒ Nothing ☐ Minimal ☐ Moderate ☐ Substantial ☐ Excessive

- a. Estimate of the number of small businesses subject to the proposed regulation:
- b. Projected costs for small businesses to comply:
- c. Statement of probable effect on impacted small businesses:

7. The cost of adopting the rule compared to not adopting the rule or significantly amending the existing rule (check option):

- ☐ substantially less than    ☐ moderately less than    ☐ minimally less than  
☐ the same as    ☒ minimally more than    ☐ moderately more than  
☐ substantially more than    ☐ excessively more than

8. The benefit of adopting the rule compared to not adopting the rule or significantly amending the existing rule (check option):

- ☐ substantially less than    ☐ moderately less than    ☐ minimally less than  
☐ the same as    ☒ minimally more than    ☐ moderately more than  
☐ substantially more than    ☐ excessively more than

#### B. Reasonable Alternative Methods

1. Other than adopting this rule, are there less costly or less intrusive methods for achieving the purpose of the proposed rule?

- ☐ yes    ☒ no

2. If yes, please briefly describe available, reasonable alternative(s) and the reasons for rejecting those alternatives in favor of the proposed rule. (Please see §25-43-4.104 for factors you must consider.)

#### C. Data and Methodology

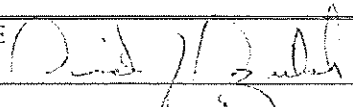
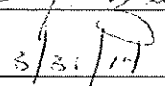
Please briefly describe the data and methodology you used in making the estimates required by this form.

*Using the paid units from claims data for all Physician Administered Drugs and Implantable Drug System Devices provided to beneficiaries for State Fiscal Year 2013 and the new fees calculated with the 6% increase, it is estimated that the financial impact to the state agency will be \$514,476.39 annually.*

#### D. Public Notice

Where, when, and how may someone present their views on the proposed rule and demand an oral proceeding on the proposed rule if one is not already provided?

*Written comments will be received by the Division of Medicaid, Office of the Governor, Walter Sillers Building, Suite 1000, 550 High Street, Jackson, MS 39201, thirty (30) days from the date of publication of public notice. All comments will be available for public review at the above address.*

SIGNATURE 	TITLE Executive Director
DATE 	PROPOSED EFFECTIVE DATE OF RULE 06/01/2014